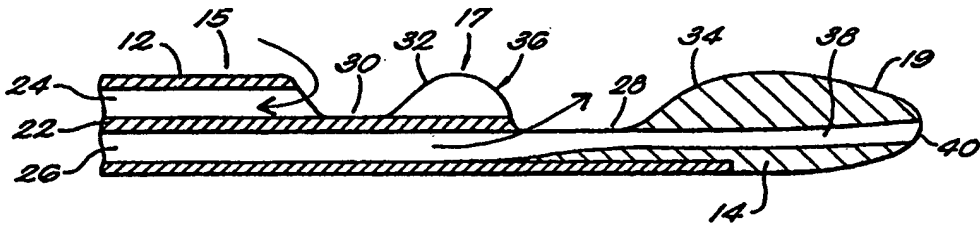


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| (54) Title: MULTIPLE LUMEN CATHETER WITH AN ENLARGED TIP <div data-bbox="292 1197 1266 1428">  </div> (57) Abstract <p>This invention is an elongate catheter (10) having one or more lumens (24, 26) therein, and at least one lumen in flow communication with an opening in the tip member (14) of the catheter. The tip member includes proximal area (15) for attachment of the tip member to the body portion (12) of the catheter, a flow passage area (17) having distal, proximal inner surfaces (32, 34) which taper outwardly from the interior of the catheter that includes a raised area (36) therebetween such that the openings are located on the same side of the catheter, and are spaced apart from each other with the raised area inbetween.</p> | | |

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MULTIPLE LUMEN CATHETER WITH AN ENLARGED TIP

Field of the Invention

The present invention relates generally to catheters for use on a human patient and more particularly to a multiple lumen catheter having an improved catheter tip. More particularly, the present invention includes a reinforced wall adjacent to a portion of the tip member and also preferably a lumen for the passage of a guide wire therethrough.

10 Background of the Invention

Single or multiple lumen catheters are well known in the medical field and are widely used in medical procedures such as hemodialysis or other procedures wherein it is desirable to inject or remove fluids through one or more lumens of the catheter. For example, in hemodialysis it is desirable to introduce blood into a vein or other vessel of a patient through a first lumen while simultaneously removing a corresponding amount of blood from the patient through a second lumen of the catheter. In certain situations, it may also be desirable to have a third lumen or fourth lumen extending through the catheter to allow a medication to be injected therethrough without interfering with the operation of the first or second lumens.

The currently available single or multiple lumen catheters frequently have an opening at the distal end thereof and one or more openings or holes along the sidewall of the catheter. During hemodialysis, the arterial or intake lumen is used to remove blood from the patient. This intake lumen typically opens along the sidewall of the catheter. In use, the side opening may occasionally become completely or partially occluded by the interior wall of the patient's blood vessel. The complete or partial occlusion of the side opening will significantly reduce the flow of blood through the intake lumen of the catheter and

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may also damage the interior wall of the patient's blood vessel.

In certain commercially available catheters, one or more relatively large side openings are used. With these
5 side openings it is typically recommended that the flow of fluid through the side opening be checked prior to hemodialysis. If the side opening is occluded, it is recommended that the catheter be rotated or otherwise repositioned. A further difficulty with the use of the
10 large single side opening is that the side opening may occasionally get caught on the tissue or the wall of the blood vessel during insertion into the patient. Yet another difficulty with the use of a large single side opening is that the catheter may kink or bend at the side opening
15 during insertion if the catheter tip meets resistance during insertion because the large side opening may weaken the column strength of the catheter.

In a commercially available catheter such as the catheter disclosed in U.S. Patent No. 4,543,087 granted to
20 Sommercorn et al., a plurality of spaced apart side openings are provided so that even if one side opening is occluded at least one of the remaining side openings may remain open. Another approach to solving the problem of occlusion is disclosed in U.S. Patent No. 4,795,439 granted
25 to Guest. In this patent, the lumens of the distal portion of the catheter are twisted such that the plurality of side openings in the catheter are not aligned in a straight line along the distal portion of the catheter.

The use of multiple side openings in a catheter
30 provides an increased likelihood that a clot may form along or in one or more of the side openings as compared to the likelihood of clotting in catheters with a single side opening for each lumen. This increased likelihood of clot formation is believed to be caused, at least partially, by
35 the presence of multiple surfaces between each of the side openings which may provide an area of reduced flow in the lumen which allows the clot to form thereon. Additionally,

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it is a common practice to prime the catheter lumens with heparin between treatments in order to decrease the likelihood of clot formation in the catheter. Priming the lumens with heparin is believed to be less effective in removing or preventing clot formation in catheters with multiple side openings because if one of the side openings is occluded by a clot, the heparin will merely flow through the side opening which provides the least resistance. There is also the possibility that the heparin may be washed out of the distal portion of the lumen of the catheter by blood which may enter one or more of the proximally located side openings to flush the heparin through the lumen and out of the catheter through one or more of the distally located side openings.

Several multiple lumen catheters are known in the art. For example, U.S. Patent No. 4,808,155 granted to Mahurkar is directed to a dual lumen catheter which is used primarily for hemodialysis. The catheter disclosed in this patent includes side by side lumens for the infusion and withdrawal of the patient's blood. As shown, the withdrawal lumen is substantially shorter than the infusion lumen to minimize the mixing of the treated and untreated blood of the patient.

In U.S. Patent No. 5,571,093 granted to Cruz et. al. A multiple lumen catheter is shown which includes a pair of side by side lumens having the distal openings to the lumens spaced apart from each other and opening on the same side of the catheter tip. One potential disadvantage of this type of catheter is that the tip of the catheter may fold over on itself during use. Additionally, a common approach to catheter placement is the Seldinger technique which requires the use of a guide wire during placement of the catheter. The design disclosed in the Cruz patent is not readily adaptable for use with this technique.

Accordingly, there is a need for a catheter capable of overcoming the problems described above as well as others,

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such as catheter whipping and the mixing of fluids from the two lumens at the tip portion of the catheter.

Summary of the Present Invention

The present invention is intended to provide an improved tip for a catheter. The catheter tip preferably minimizes whipping or bending of the catheter tip while reducing the mixing of fluids from the catheter. Additionally, the present invention enables the physician to insert the catheter using conventional placement techniques while reducing the likelihood of positional occlusion of the catheter.

According to a preferred form of the present invention, the catheter includes a pair of side by side lumens which extend from the proximal end portion of the tubing to the distal end portion of the tubing. The tip portion is preferably attached to the distal end portion of the tubing and includes distal and proximal end portions thereon. The preferred form of the catheter is a dual lumen catheter having at least one generally D shaped lumen therein. The catheter preferably includes a blood return or first lumen which extends between the proximal end portion of the catheter and the distal end portion of the catheter tip. The other lumen is preferably an intake or second lumen which extends between the proximal end portion of the catheter and a side opening generally at the interconnection of the distal end portion of the catheter and the proximal end portion of the catheter tip. The tip portion preferably includes distal and proximal end portions wherein the connection portion is located along the proximal end portion of the tip and the distal end portion is generally bulbous shaped with a relatively small guide wire passing lumen extending therethrough. The sidewall of the tubing portion of the distal end portion of the catheter preferably extends beyond the opening of the second lumen on the side of the catheter which is opposite opening to reinforce the catheter to minimize buckling.

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Another object of the present invention is to prevent clotting by providing a side opening in the sidewall of a catheter which is shaped and oriented to be essentially self flushing such that external fluid flow may pass
5 directly from the proximal side of the side opening to the distal side of the side opening without interruption.

Yet another object of the present invention is to reduce vessel wall occlusion by providing a side opening which maximizes the open passageway for fluid flow even
10 when a portion of the slot is occluded by or sucked against a portion of the vessel wall.

Brief Description of the Drawings

Figure 1 is an elevated view of a catheter of the present invention;

15 Figure 2 is an enlarged elevated view of the distal portion of the embodiment shown in Figure 1;

Figure 3 is an enlarged side view of the distal portion of the embodiment shown in Figure 1;

20 Figure 4 is an enlarged cross-sectional view of the distal portion of the embodiment shown in Figure 1, taken generally along lines 4-4 of Figure 2;

Figure 5 is a cross-sectional view of the embodiment shown in Figure 1 taken generally along lines 5-5 of Figure 2;

25 Figure 6 is a cross-sectional view of the embodiment shown in Figure 1 taken generally along lines 6-6 of Figure 2; and

Figure 7 is an end view of the catheter of Figure 1.

Description of the Preferred Embodiments

30 The preferred form of the overall catheter assembly 10 of the present invention is generally shown in the drawings. The catheter assembly 10 generally includes an elongate and slightly oval-shaped body portion 12 having a tip member 14 on the distal end thereof and a Y-shaped
35 connector hub 16 on the proximal end thereof. As shown in

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Figure 1, the proximal end of the Y-connector includes extension members 18 and 20 thereon. The extension members 18 and 20 may be bent as shown or straight (not shown). As used herein, the term "proximal" is intended to refer to the end or portion of a member which is normally oriented or positioned away from the patient while the term "distal" refers to the end or portion of a member in use which is nearest to the patient. Although the preferred form of the present invention is described herein with respect to multiple lumen catheters, it is intended that the present invention may also be used with nearly any catheter having one or more lumens therein including angiographic, central venous, hemodialysis or various other catheters.

The body portion 12 of the preferred embodiment of the catheter assembly 10 is hollow except for a generally flat, longitudinal septum 22 which divides the interior of the hollow cylinder into two preferably parallel lumens 24 and 26, with each lumen, 24 and 26, having a generally D-shaped cross section. As illustrated by the arrows in Figure 4, the lumen 24 is the blood intake or arterial lumen, and the lumen 26 is the blood return or venous lumen when this invention is used for a procedure such as hemodialysis.

At the distal end of the catheter assembly 10, the exterior surface of the body portion 12 preferably merges smoothly into the tip member 14. The body of the tip member 14 is preferably formed by injection molding and may be adhesively, heat or otherwise attached or bonded to the distal end portion of the body portion in a conventional manner. Additionally, the tip may also be insert molded directly onto the distal end portion of the body portion. The tip member preferably includes three areas. The proximal area 15 is the connection area where the tip member 14 and body portion 12 are interconnected. As shown in the drawings, the proximal area 15 is generally staggered so that the outer wall of the body portion 12 which is oriented adjacent to the side of the intake lumen 24 is proximal to the portion of the body portion 12 which

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forms the septum 22 and the outer wall of the body portion 12 which is adjacent to the return lumen 26 extends beyond the septum 22 and outer wall of the body portion which is adjacent to the intake lumen. As shown in the drawings, the proximal side of the proximal area 15 generally forms the opening 30 for the intake lumen 24.

The middle portion of the tip member 14 is generally referred to as the flow passage area 17. The flow passage area 17 preferably includes a pair of flow directing inner surfaces. The proximal inner surface 32 directs the flow of fluid from the blood vessel of the patient into the catheter when the catheter is used for hemodialysis and has sufficient surface area and tapered surfaces to minimize the likelihood that the opening 30 for the intake lumen 24 will not be caught against the wall of the blood vessel. Additionally, the proximal inner surface 32 is shaped to disperse any fluids which are injected into the blood vessel of the patient through this lumen when the flow of fluids is reversed. The distal inner surface 34 of the flow passage area 17 is adjacent to the opening 28 for the return lumen 26 to disperse and direct the fluids passing from the opening 28 into the blood vessel of the patient when the catheter is used for hemodialysis or the injection of fluids or medications into the patient. As with the proximal inner surface 32, the distal inner surface 34 is shaped to minimize the likelihood that the opening 28 will be drawn against the wall of the blood vessel if fluids are drawn into the catheter through the opening 28 because of the shape of the distal inner surface 34. Additionally, the existence of the guide wire lumen 38 in fluid communication with the return lumen 26 will prevent the opening 28 from being drawn up against the wall of the blood vessel because fluid will continue to flow through the distal most opening 40 which is preferably located on the distal end of the tip member 14. As shown, the flow passage area 17 also includes a raised area 36 which functions to reduce the likelihood that fluids will be intermixed between the openings 28 and

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30 because fluids injected through the opening 30 will contact and be dispersed by the proximal inner surface 32 and the raised area 36.

5 The final area of the tip member 14 is the nose area 19. This area is an enlarged area located on the distal end portion of the tip member 14. The nose area 19 is a generally bullet shaped area which functions to disperse fluids from the return lumen and also includes the guide wire lumen 38 extending therethrough.

10 The outer diameter of the tip member 14 decreases from the proximal area 15 of the nose area 19. At the proximal portion of the nose area 19, the diameter of the tip member is approximately equal to or slightly less than the diameter of the body portion 12 of the catheter assembly
15 10. As shown in Figure 4, the interconnection of the tip member 14 and the body portion rely on the engagement of the walls of the body portion and the tip member which as mentioned above, may be adhesively or otherwise bonded together in a conventional manner. The wall of the body
20 portion 12 which is opposite to the opening 30 extends into the tip member 14 and preferably forms a surface for binding the components together as well as a surface which adds longitudinal strength to the tip member 14. In the preferred form of this invention, the tip member 14 is
25 formed of a relatively soft material so as to minimize the potential for injury to the wall of the blood vessel while the body portion is preferably stiffer than the tip member 14 to provide greater columnar strength to the catheter assembly to allow for the insertion of the catheter into
30 the body of the patient.

As shown in Figures 2 and 3, the openings 28 and 30 of the lumens of the catheter preferably extend the entire width of the tip member 14 and are separated longitudinally along the tip member 14 by the raised area 36.
35 Additionally, the relative area of the openings 28 and 30 at the proximal inner surface 32 and distal inner surface 34 is preferably greater than the area of the lumens 24 and

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26 along the length of the body portion 12. The proximal and distal inner surfaces, 32 and 34, preferably curve radially away from the axis of the tip member 14. The shape of the proximal and distal inner surfaces 32 and 34, generally determines the shape of the openings 30 and 28 respectively. These openings are preferably formed to extend more than 180 degrees around the circumference of the tip member 14. Therefore, fluids delivered outwardly through the lumens 24 and 26 pass around and over a large portion of surface area of the raised area 36 and nose area 19. Therefore, the tendency for the tip member to whip in the blood vessel during use is reduced. The proximally positioned portion of the raised area 36 and nose area 19 adjacent to the openings 28 and 30 are each gradually built up in the distal direction to define a preferably uniform arc terminating along the outer surface of the tip member 14. In the preferred form of this invention, the radius of this arc is relatively short and is preferably as large as the intake and return lumens, 24 and 26 respectively. Additionally, the taper on the proximal side of each of the openings 28 and 30 is much sharper than the gradually tapered surfaces on the distal side of the openings formed by the proximal and distal inner surfaces, 32 and 34.

While the foregoing description has been drawn to the presently preferred embodiment of the present invention, it should be understood by those skilled in the art of the present subject matter that various modifications may be made to the present invention without departing from the scope and spirit of the invention which is defined by the following claims.

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MULTIPLE LUMEN CATHETER WITH AN ENLARGED TIP

Claims

1. An elongate catheter comprising:
an elongate body portion formed by a circumferential sidewall with a septum extending therebetween and having a longitudinal axis and distal and proximal end portions thereon;
5 a first lumen in said body portion extending between said proximal end portion and said distal end portion;
a second lumen in said body portion extending between said proximal end portion and said distal end portion;
10 a tip member extending from said distal end portion of said body portion;
said tip member including a proximal area connected to said distal end portion of said body portion and a flow passage area distally of said proximal area;
15 said tip member further including a nose area on said tip member wherein said nose area is located distally of said flow passage area and includes a lumen extending therethrough; and
20 a plurality of openings on said tip member which are interconnected with said first and second lumens and said plurality of openings are spaced apart from each other by a raised area on said flow passage area of said tip member.
2. The catheter of claim 1 wherein said body portion includes said first and second lumens therein formed by said septum and said circumferential sidewall and extending longitudinally along said body portion, and said second
5 lumen extends between said proximal end portion and a location between said distal end portion of said body portion and said raised area on said flow passage area of said tip member.

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3. The catheter of claim 1 wherein said second lumen extends between said proximal end portion and a location distally of said raised area on said flow passage area of said tip member.

4. The catheter of claim 3 wherein said second lumen is in flow communication with at least one of said plurality of openings and said lumen in said nose area on said tip member and wherein said at least one of said
5 plurality of openings opens on said tip member between said raised area of said flow passage area and between said nose area of said tip member.

5. The catheter of claim 1 wherein the interconnection of said tip member and said body portion is staggered such that the portion of said sidewall which is adjacent to first lumen is shorter than the portion of said
5 sidewall which is adjacent to said second lumen.

6. The catheter of claim 1 wherein said body portion is interconnected with said tip member and the interconnection of said tip member and said body portion is staggered such that the interconnection between said septum
5 and said tip member is intermediate to the interconnection of a portion of said sidewall adjacent to said first and second lumens and wherein the interconnection of said first lumen with said tip member is proximal of the interconnection of said second lumen and said tip member.

7. The catheter of claim 1 wherein said body portion is interconnected with said tip member and said septum is interconnected with said raised area of said flow passage area of said tip member and a portion of said sidewall
5 adjacent to said second lumen is interconnected to said tip member at a location distally of said interconnection of said septum and said tip member.

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8. The catheter of claim 1 wherein said lumen of said nose area extends to the distal end of said tip member to form an opening thereon.

9. The catheter of claim 1 wherein the circumference of body portion is greater than the circumference of said tip member adjacent to at least a portion of said flow passage area.

10. The catheter of claim 1 wherein said tip member includes a proximal inner surface adjacent to said first lumen and said proximal inner surface tapers outwardly from said septum to form said raised area in said flow passage area of said tip member.

11. The catheter of claim 10 wherein said proximal inner surface forms an arcuate raised area on said flow passage area of said tip member.

12. The catheter of claim 1 wherein said tip member includes a distal inner surface adjacent to said second lumen and said distal inner surface tapers inwardly from said nose area to a location adjacent to said raised area of said tip member.

13. The catheter of claim 12 wherein said distal inner surface forms an arcuate raised area on said flow passage area of said tip member.

14. An elongate catheter comprising:
an elongate body portion formed by a circumferential sidewall with a septum extending therebetween and having a longitudinal axis and distal and proximal end portions thereon;

a first lumen in said body portion formed between at least a portion of said circumferential sidewall and

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said septum and extending between said proximal end portion and said distal end portion of said body portion;

10 a second lumen in said body portion formed between at least a portion of said circumferential sidewall and said septum and extending between said proximal end portion and said distal end portion of said body portion;

15 a tip member extending from said distal end portion of said body portion;

 said tip member including a proximal area connected to said distal end portion of said body portion and a flow passage area distally of said proximal area;

20 said tip member further including a nose area on said tip member wherein said nose area is located distally of said flow passage area and includes a lumen extending therethrough; and

 a first opening on said tip member in flow communication with said first lumen and a second opening on
25 said tip member in flow communication with said second lumen and said lumen in said nose area forming a third opening on said tip member and wherein said first and second openings are spaced apart from each other on said tip member by a raised area of said flow passage area
30 wherein said raised area is formed by at least part of a proximal inner surface which tapers outwardly from said septum.

15. The catheter of claim 14 wherein the interconnection of said tip member and said body portion is staggered such that the portion of said sidewall which is adjacent to first lumen is shorter than the portion of said
5 sidewall which is adjacent to said second lumen.

16. The catheter of claim 14 wherein said body portion is interconnected with said tip member and the interconnection of said tip member and said body portion is staggered such that the interconnection between said septum
5 and said tip member is intermediate to the interconnection

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of a portion of said sidewall adjacent to said first and second lumens and wherein the interconnection of said first lumen with said tip member is proximal of the interconnection of said second lumen and said tip member.

17. The catheter of claim 14 wherein said body portion is interconnected with said tip member and said septum is interconnected with said raised area of said flow passage area of said tip member and a portion of said
5 sidewall adjacent to said second lumen is interconnected to said tip member at a location distally of said interconnection of said septum and said tip member.

18. The catheter of claim 14 wherein the circumference of body portion is greater than the circumference of said tip member adjacent to at least a portion of said flow passage area.

19. The catheter of claim 14 wherein said tip member include said proximal inner surface adjacent to said first lumen and said proximal inner surface tapers outwardly from said septum to form said raised area in said flow passage
5 area of said tip member and said proximal inner surface forms an arcuate raised area on said flow passage area of said tip member.

20. The catheter of claim 14 wherein said tip member includes a distal inner surface adjacent to said second lumen and said distal inner surface tapers inwardly from said nose area to a location adjacent to said raised area
5 of said tip member.

21. The catheter of claim 20 wherein said distal inner surface forms an arcuate raised area on said flow passage area of said tip member.

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22. The catheter of claim 14 wherein said first and second openings are spaced apart from each other and are located on the same side of the catheter.

said septum and extending between said proximal end portion and said distal end portion of said body portion;

a second lumen in said body portion formed between at least a portion of said circumferential sidewall and said septum and extending between said proximal end portion and said distal end portion of said body portion;

a tip member extending from said distal end portion of said body portion;

said tip member including a proximal area connected to said distal end portion of said body portion and a flow passage area distally of said proximal area;

said tip member further including a nose area on said tip member wherein said nose area is located distally of said flow passage area and includes a lumen extending therethrough; and

a first opening on said tip member in flow communication with said first lumen and a second opening on said tip member in flow communication with said second lumen and said second lumen in said nose area forming a third opening on said tip member and, wherein said first and second openings are spaced apart from each other on said tip member by a raised area of said flow passage area wherein said raised area is formed by at least part of a proximal inner surface which tapers outwardly from said septum.

15. The catheter of claim 14 wherein the interconnection of said tip member and said body portion is staggered such that the portion of said sidewall which is adjacent to first lumen is shorter than the portion of said sidewall which is adjacent to said second lumen.

16. The catheter of claim 14 wherein said body portion is interconnected with said tip member and the interconnection of said tip member and said body portion is staggered such that the interconnection between said septum and said tip member is intermediate to the interconnection

22. The catheter of claim 14 wherein said first and second openings are spaced apart from each other and are located on the same side of the catheter.

23. An elongate catheter comprising:

an elongate body portion formed by a circumferential sidewall with a septum extending therebetween and having a longitudinal axis and distal and proximal end portions thereon;

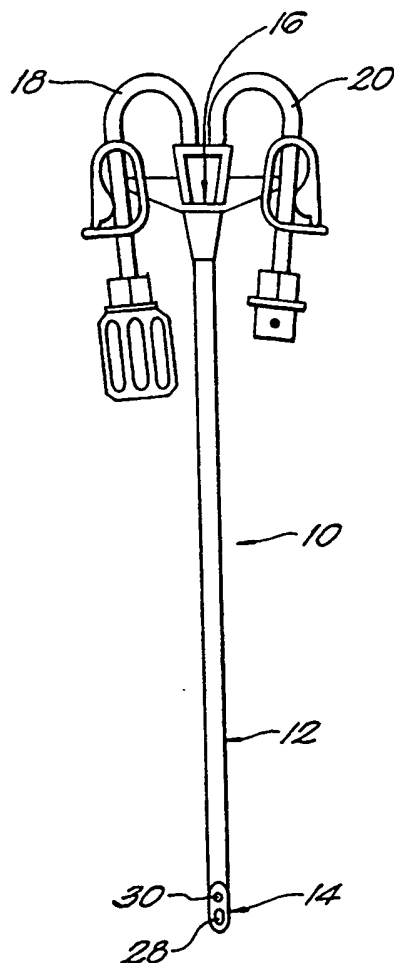
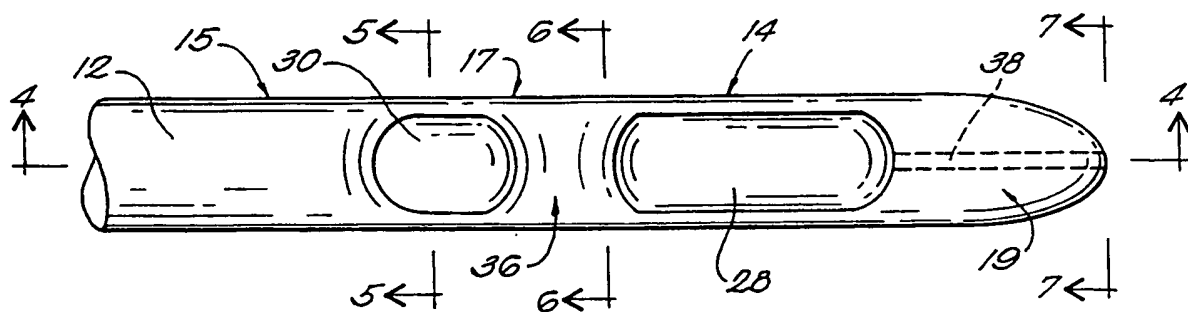
a first lumen in said body portion formed between at least a portion of said circumferential sidewall and said septum and extending between said proximal end portion and said distal end portion of said body portion;

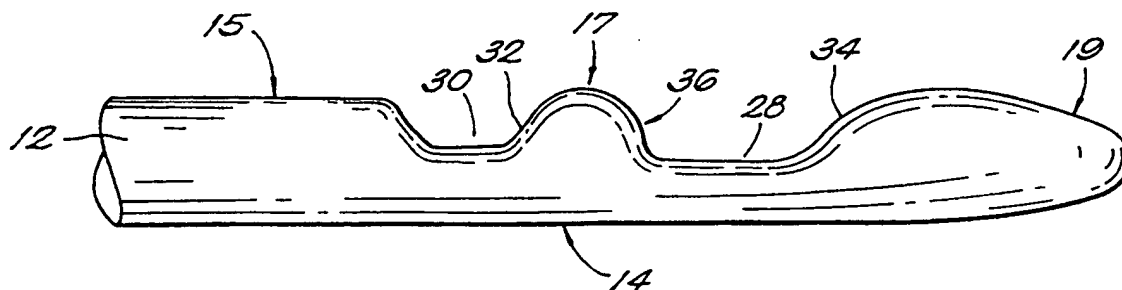
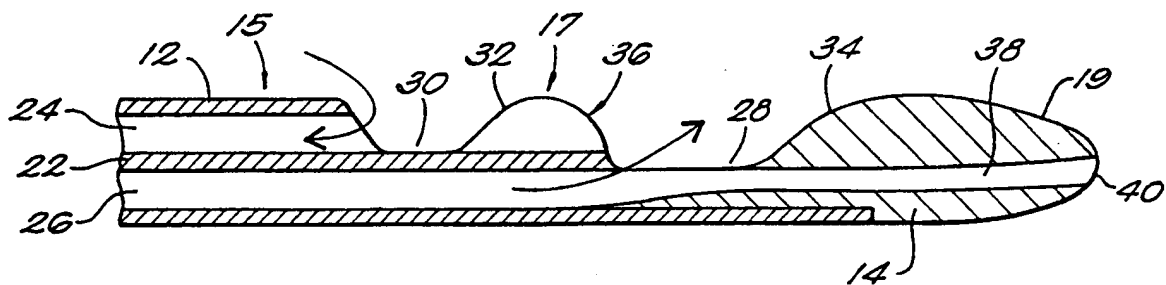
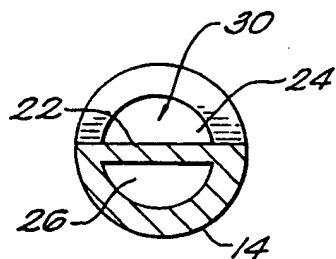
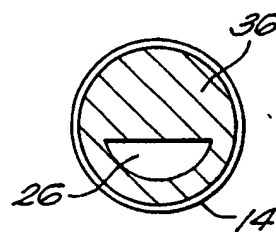
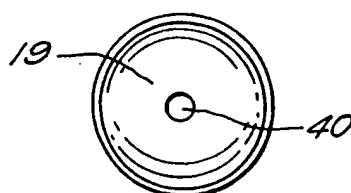
a second lumen in said body portion formed between at least a portion of said circumferential sidewall and said septum and extending between said proximal end portion and said distal end portion of said body portion;

a tip member extending from said distal end portion of said body portion and including a proximal area connected to said distal end portion and a flow passage area distally of said proximal area;

said tip member further including a nose area having a distal nose end portion wherein said nose area is located distally of said flow passage area and includes a lumen extending therethrough to said distal nose end portion; and

a first opening on said tip member in flow communication with said first lumen and a second opening on said tip member in flow communication with said second lumen and said second lumen in said nose area forming a third opening at said distal nose end portion and, wherein said first and second openings are spaced apart from each other on said tip member by a raised area of said flow passage area wherein said raised area is formed by at least part of a proximal inner surface which tapers outwardly from said septum.

**FIG. 1****FIG. 2**
SUBSTITUTE SHEET (RULE 26)

**FIG. 3****FIG. 4****FIG. 5****FIG. 6****FIG. 7**

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/01969

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 3/00

US CL : 604/35, 43

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/35, 39, 43, 264, 268, 284, 538

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | US 4,995,865 A (GAHARA et al.) 26 February 1991, Fig. 2. | 1, 14 |
| A | US 5,472,417 A (MARTIN et al.) 05 December 1995, Fig. 3. | 1, 14 |
| A | US 5,380,276 A (MILLER et al.) 10 January 1995, Fig. 2. | 1, 14 |
| A | US 5,685,867 A (TWARDOWSKI et al.) 11 November 1997, Figs. 3-12. | 1, 14 |
| X | US 5,571,093 A (CRUZ et al.) 05 November 1996, Figs. 11-15. | 1-14 |
| Y | US 5,451,206 A (YOUNG) 19 September 1995, Figs. 12-14 for the third opening. | 14 |



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

24 MARCH 1999

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